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EXAMINER

AUDET, MAURY A

ART UNIT PAPER NUMBER

1654

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/019,482

Applicant(s)

PRIVE, GIL

Examiner

Maury Audet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/19/02, 4/30/02</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Election/Restrictions***

Applicant's amendment and response of May 14, 2004 is acknowledged. Claims 1-12 are pending. Applicant traverses that the restriction requirement is defective because it does not present any alternative groups of claims. Applicant's arguments have been considered, but are not found persuasive. Since the number of potential conjugates and peptides capable of being used therein is unclear, no groups could necessarily be formed. Rather only the broad, undefined "peptide conjugates" could be identified as a group, from which the Examiner required Applicant to elect a single "peptide conjugate" as the invention, rather than an election of species (see page 4 of the restriction). Applicant has not elected such a conjugate of record.

Applicant has asserted that an interview between the Examiner and Applicant on April 28, 2004 changed the restriction requirement to be an election of species (page 2, response). The Examiner does not recall changing the entire scope of the restriction requirement to be an election of species, since clearly a search the gamut of peptides that could be used in the conjugates would pose such a severe undue burden on the Examiner. **However, since the only distinctly searchable peptide in the claims or in the Sequence Listing is SEQ ID NO: 1, and in order to advance prosecution, the Examiner is willing to search the claims as drawn to a "peptide conjugate" of SEQ ID NO: 1 (the only searchable peptide) and the elected detergent species LPD-16 of Example 1 from the specification.**

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. In this case, Applicant has elected LPD-16 as the detergent species.

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However, no claims are currently drawn to this species, and the claims will need to be amended accordingly. Currently, claim 1, as drawn to a peptide conjugate of SEQ ID NO: 1, is generic.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

### ***Claim Rejections - 35 USC § 112 1<sup>st</sup> Scope***

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the peptide of SEQ ID NO: 1 in the invention's "peptide conjugate", does not reasonably provide enablement for any other peptides in the "peptide conjugate". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in

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the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring “ingenuity beyond that to be expected of one of ordinary skill in the art” (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that “... where a statement is, on its face, contrary to generally accepted scientific principles”, a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971)). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988)). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for any peptide in the “peptide conjugate” of the invention, other than the peptide of SEQ ID NO: 1

*The nature of the invention:* The invention is drawn to a “peptide conjugate” wherein “said peptide moiety of the conjugate compris[es] a first end and a second end, wherein said first end is covalently linked to a first aliphatic hydrocarbon moiety and said second end is covalently linked to a first aliphatic hydrocarbon moiety . . .”.

*The state of the prior art and the predictability or lack thereof in the art:*

Amino acids range from common amino acids, to uncommon amino acids, and even “important amino acids, such as the neurotransmitter y aminobutyric acid, that have no relation to proteins.” (Online-Medical Dictionary. “Amino acid”. <http://cancerweb.ncl.ac.uk/cgi-bin/omd?query=amino+acid>. 13 Nov. 1997).

*The amount of direction or guidance present and the presence or absence of working examples:* Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). The specification describes the use of only

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the peptide of SEQ ID NO: 1 in the “peptide conjugate” (see page 15-21, Examples).

Specification page 8, describes that the “novel lipopeptide detergents” have a “peptide scaffold [that] is not particularly limited with respect to its amino acid sequence. However, the amino acid sequence is selected so as to permit formation of the peptide scaffold into an amphipathic  $\alpha$ -helical conformation. Generally, the peptide will comprise a mixture of hydrophobic and hydrophilic regions” where “[t]he number of amino acids in the peptide scaffold is variable”.

It is not clear what peptides will form this “amphipathic  $\alpha$ -helical conformation” (which the specification describes as in such a way as essential) and determining which peptides would form such and then determine which would be capable of working within the invention as claimed, would require undue experimentation by one of skill in the art.

*The breadth of the claims and the quantity of experimentation needed:* The claims are drawn broadly (claim 1) to a “peptide conjugate” wherein “said peptide moiety of the conjugate compris[es] a first end and a second end, wherein said first end is covalently linked to a first aliphatic hydrocarbon moiety and said second end is covalently linked to a first aliphatic hydrocarbon moiety . . .”. With the substantial variability among what amino acids may be encompassed by such claim language, and to form such into the essential “amphipathic  $\alpha$ -helical conformation”, and then to work properly with the invention’s “peptide conjugate”, it is not clear as to what may be included (i.e. common, uncommon amino acids, or non-peptide amino acids such as “ $\gamma$  aminobutyric acid”) and the ultimate peptide structure, so as to work in the invention as claimed. Absent sufficient teachings in the specification or art sufficient to overcome the teachings of unpredictability in the art as to enablement on the use of any amino acid residues in

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the peptide moiety; it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

***Claim Rejections - 35 USC § 112 2nd***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is unclear what is contemplated as the peptide(s), and thus the possible “peptide conjugate” of the invention, based on Applicant’s language “said peptide moiety of the conjugate comprising a first end and a second end, wherein said first end is covalently linked to a first aliphatic hydrocarbon moiety and said second end is covalently linked to a first aliphatic hydrocarbon moiety . . .”. Claim 4 adds that such a peptide may be 15-35 amino acids, which unfortunately does not clarify the structure/sequence of the peptides capable of use in the invention. It is unclear what the invention is (structure of the “peptide conjugate”) since the structure/sequence of the peptide(s) is/are unclear (and thus a sequence database/structure search and examination of such is not possible).

***Allowable Subject Matter***

The “peptide conjugate” of Claim 6, conjugated to the elected detergent species LPD-16 (claims need amending to incorporate), would likely be allowable if rewritten into independent

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form (notwithstanding any § 112 issues as to the structure of the conjugate). A “peptide conjugate” consisting of SEQ ID NO: 1 (corresponding to the peptide of claim 6) and the elected detergent species LPD-16 was not taught or reasonably suggested by the prior art. Since no other detergent species are distinctly claimed, an additional search of other detergent species was not possible. However, if the claims were amended to incorporate other detergent species, the Examiner will consider a search of the peptide of SEQ ID NO: 1 conjugated to these detergent species.

### *Conclusion*

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA  
7/26/04



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PRIMARY EXAMINER